Center for Biologics Evaluation and Research

Center for Drug Evaluation and Research

eCTD Viewer System (EVS)

EVS Environment Specification v1.0
Draft

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1. INTRODUCTION

The FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are responsible for reviewing new applications for biological and pharmaceutical products. The Electronic Common Technical Document (eCTD) defines a new standard for companies to submit these applications. The eCTD has its origins in the paper-based Common Technical Document (CTD) standard developed under the auspices of the International Conference on Harmonisation (ICH).

In order to facilitate the review of eCTD submissions in the US, CBER and CDER have initiated the development of the eCTD Viewer System (EVS). The EVS will be comprised of numerous functionalities, and supported by software that can receive, validate, and transform the XML files submitted by industry into a practical view. The EVS will be integrated with, and launched from, existing electronic document rooms (EDRs). The design of the EVS will leverage the existing information technology infrastructure to minimize redundancy and maximize utility.

1.1 PURPOSE

This document provides an overview of the resource requirements to support the EVS development, test, and deployment environments.

1.2 BACKGROUND

The EVS is currently in the development phase, supported by resources located at Booz Allen's Parklawn Office. As the application moves to the production phase, it is intended to migrate to the production environment located in the CDER hosting facility with communication to both CDER and CBER EDRs.

1.3 REFERENCE DOCUMENTS

The following documents listed below have been used in the development of this document.

- EVS Software Requirements Specification v1.1
- EVS Design Document v1.1
- CDER OIT Portal Standard Operating Procedures: Unix production and Test Environments
- Unix Infrastructure: OIT Portal Production Environment Configuration
- EVS Performance Baseline v1.1

1.4 DOCUMENT ORGANIZATION

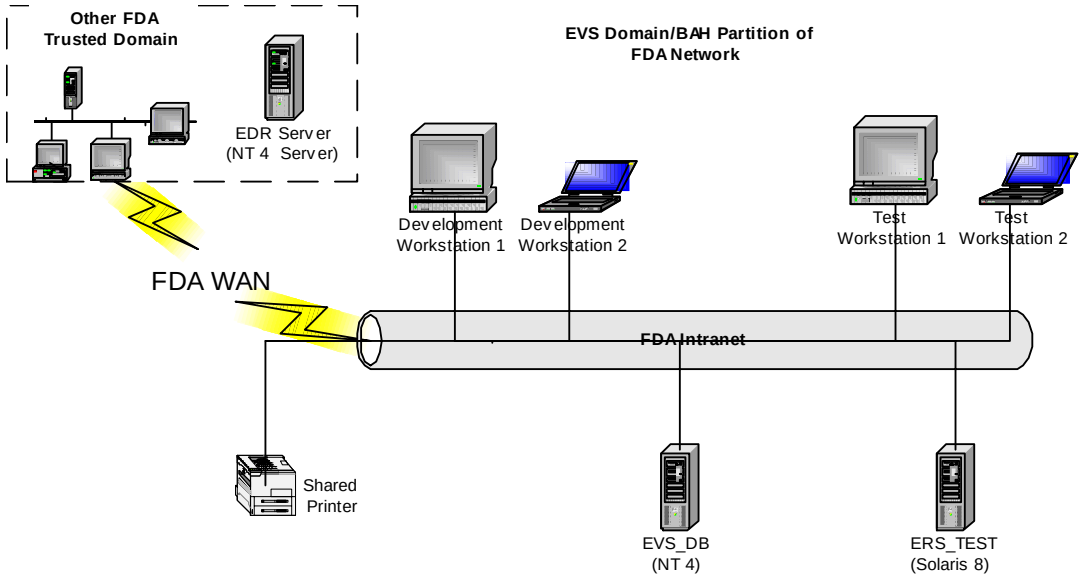
This document is organized as follows:

- **Section 1. Introduction** — Describes the purpose, background, references, and organization of this document.
- **Section 2. Development and Test Environment** — Outlines the resources and anticipated needs for the development and testing of the EVS in the CDER environment.
- **Section 3. Deployment Environment and Plan** — Outlines the resources and anticipated needs for deployment of the EVS in the CDER environment.
- **Section 4. Capacity Planning** — Provides information on the capacity planning estimates used for the deployment plan.

2. HARDWARE AND SOFTWARE ENVIRONMENT

To offset costs associated with replicating the production environment, the EVS development and test environments will be partitioned to accommodate development, testing, and user acceptance testing (UAT) as separate instances. The key difference between the development and test environment is that the development server (EVS_DEV) will contain development tools and the test server (EVS_TEST) may or may not share the tools with the development environment. Figure 2-1 depicts a logical view of this shared environment.

Figure 2-1: EVS Development and Test Environment (Logical View)



The development and test environments will reside on the XXXX domain of the FDA sub-network located at the XXXX facility. The production environment will reside in the CDER hosted facility in Parklawn.

Table 2-1 provides the hardware configuration for the servers and workstations in the development and test environments. The hardware components reflect the minimum requirements to properly support, run the intended software, and develop within the environment.

Table 2-1: Hardware Configuration

Server	Instance	Operating System/ Primary Software	RAM (MB)	DISK (GB)	CPU
UNIX	For DEV_APP For TEST_APP For TEST_DB For CDER_EDR	• Solaris 8 • Oracle 9i AS	1024	20	P3 - 500 MH+
NT 1	For DEV_DB	• Windows 2000 • Oracle 7.3.4	1024	40	Dual P3 - 500 MH+
NT 2	For CBER DEV_EDR For CBER TEST_EDR For CBER _UAT_EDR	• Windows 2000 • Oracle 7.3.4	2 GB	200 G	P3 - 500 MH+
Development Workstations	N/A	• Windows 2000 • Oracle 9i AS	512	30	P4 - 1.7G+
Test / UAT Workstations	N/A	• Windows 98 • Windows 2000	128	10	P3 - 300MH+
FDA Reviewers Workstation	N/A	**Details in Table 2-5**			

Table 2-2 provides detailed software configuration requirements for the development, test, and production environments.

Table 2-2: Software Configuration

Software/Tools	EVS_DEV_APP	EVS_TEST_APP	EVS_PROD_APP	Development Workstation	User Workstation
Microsoft IIS 5.0				X	
Microsoft Internet Explorer 5.5	X	X	X	X	X
Development Tool (IDE) see Table 2-3.	X	X	X	X	
Oracle 7.3.4 Server	X				
Oracle 8i JDBC drivers (Type III or IV)	X	X		X	
JDK 1.4 for Windows 2000				X	X
JAVA Plugin 1.4.1_01 for Windows 2000				X	X
JAVA Runtime 1.4.1 for Windows 2000					X
J2EE 1.3 for Windows 2000				X	
JDK 1.4 for Solaris		X	X		
Oracle 9 Server		X	X		

As noted in the table above, developers need specialized tools to assist in the development of the software. The software tools used during development are identified in Table 2-3. Since this software configuration changes as technology improves, upgrades may occur during the software development lifecycle. This information will be recorded and any modifications will be maintained in the system documentation.

Table 2-3: Development Software Toolkit

Software	Purpose	Upgrade Candidate	Future Options	Comments
ANT v.1.5	Build Tool	Yes	v.1.6	Evaluation required
Oracle 9i AS v.2.0	Application server	No		Needs JRE
JDK v.1.4.0 01; build 1.4.0 01-b03	Java Developer Kit	No		Includes JRE
Jikes v.1.5	Compiler	Yes	v.1.6	Upgrade under evaluation
TURBO XML v.2.3	XML Editor	No		
Rational Rose 2002	UML Modeling	No		
Erwin v.3.5.2	Data Modeling	Yes	v.4.0	Requires additional funds
J2EE v.1.3	Library	No		
Oracle 7.3.4	Database Server	No		CBER is currently v.7.3.4
Apache	Web Server	No		
Eclipse	IDE	N/A		

Software tools also support the software development process throughout the lifecycle. These tools provide an automated way for the team to manage and control changes as well as establish and maintain traceability throughout the process. Table 2-4 identifies the software supporting the software development lifecycle.

Table 2-4: Process Software Tools

Software	Purpose	Upgrade Candidate
Caliber-RM	Requirements Management Tool	N/A
Test Director	Test Management Tool	N/A
Version Manager, Tracker	Version Management and CCR Tracking	N/A
Standard OIT PC Software, including MS Project, Word, Excel, Power Point	Documentation, drawing, scheduling, spreadsheet, and presentation tools	As required

Table 2-5 outlines the basic configuration to support the EVS from a common user workstation. This configuration represents the minimum requirements for the most basic needs. As download and viewer needs increase, additional disk space is required. For optimized performance, as outlined the EVS Performance Baseline v1.1, an end user should be equipped with the standard hardware and software provided by the FDA. End users participating in UAT should also ensure that their desktops include standard hardware and software.

Table 2-5: End User Desktop Configuration

Workstations	RAM (MB)	DISK (GB)	CPU	Operating System/Software
Basic configuration	64	50MB (w/o downloaded documents)	Pentium II +	• Win 98/NT/2000 • Microsoft Internet Explorer 5.5 • Java J2SE v 1.4.1_01

3. PRODUCTION ENVIRONMENT PLAN

EVS v1.0 will be deployed in the CDER hosting facility and interface with other applications (i.e., EDRs) in both CDER and CBER. FDA reviewers will access the EVS application from the EDR to maintain current security architecture.

Figure 3-1 illustrates the logical data flow for the EVS shared production environment. All environments will simulate this data flow.

Figure 3-1 EVS Logical Data Flow

Diagram deleted for security

EVS deployment details are outlined in Table 3-1 and provide information related to the initial architecture. Eventually the number of submissions, reviewers, and downloads will gradually increase, and it is anticipated that the amount of data will exceed the initial deployment environment resources in that timeframe. Section identifies metrics to monitor the activity to ensure capacity

The computing specifications are based on first year estimates outlined in the Capacity Planning section for the initial EVS 1.0 deployment environments.

Table 3-1: EVS Deployment Details

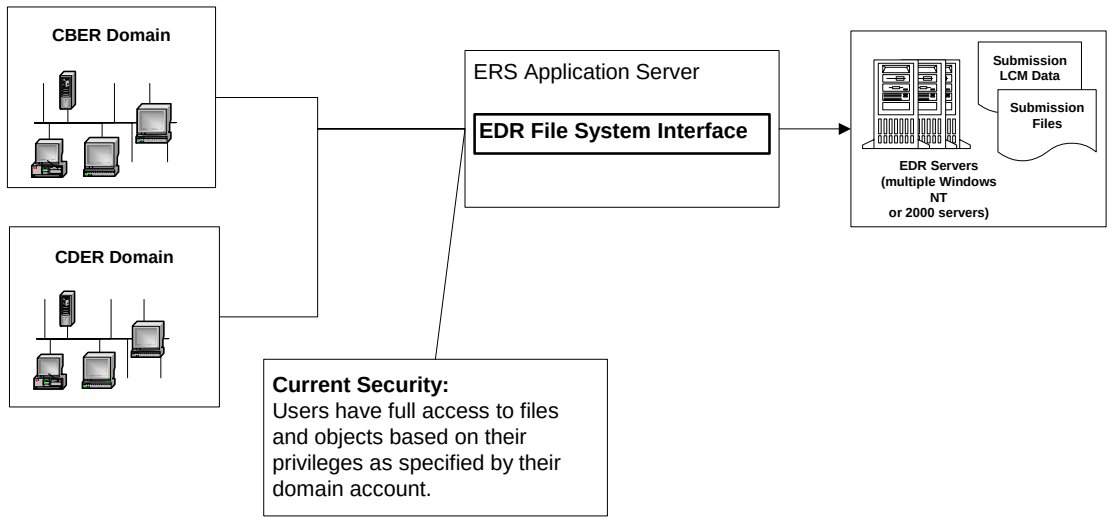
Description	Hardware	Software
EVS v1.0 exists in CDER's UNIX environment, sharing with other FDA projects	• Shared 280R Sun Server • 2 900-MHz UltraSPARC III Processors (up-to 8) • 8-MB External Cache per Processor • 2 GB Memory • 1 10/100BASE-T Self-Sensing Ethernet Port	• Oracle9*i*AS Containers for J2EE • Oracle9i Database Server • Solaris 9+ • Oracle 9i Client

3.1 FILE SYSTEM ACCESS

Users will be able to access an eCTD application through the EDR. The EDR will authenticate user access rights and display an icon to access a specific eCTD application. Users currently have access to all files within the application. Future security enhancements may include restricting a user's access based on their role within the EDR.

A user will not be able to go directly to the Center file server to retrieve application files. Figure 3.1-1 depicts a user's access to an application and its submissions.

Figure 3-2: User Access



3.2 FDA REVIEWER WORKSTATION CONFIGURATION

Table 3.2-1 outlines the basic foundation needs to support the EVS. As download and viewer needs increase, additional disk space is required. For optimized performance, as outlined the Performance Baseline Document v1.1, an end user should be equipped with the standard hardware and software provided by the FDA.

Table 3.2-1: End User Desktop Configuration

End User Workstation	RAM (MB)	DISK (GB)	CPU	Operating System/Software
Basic configuration	64	50MB (w/o downloaded documents)	Pentium II +	• Win 98/NT/2000 • Microsoft Internet Explorer 5.5+ • Java J2SE v 1.4.1_01
Optimal configuration	128	1GB	Pentium III+	• Win 98/NT/2000 • Microsoft Internet Explorer 5.5+ • Java J2SE v 1.4.1_01

4. CAPACITY PLANNING

The following are figures for the minimum memory and disk space needed for the EVS database and application servers. It is estimated that the required amount of memory for the application server will be 200MB and will require 2 GB of disk space.

The database server will require 2GB of memory and 6 GB disk space in its first year of operations. This estimate is an estimate for disk space used by the EVS during the first year. The numbers in this estimate have been derived from test data received by the FDA.

Table 4-1: EVS 1.0 Disk ad Memory Requirements

Server	Memory	Disk Space
Application Server	200MB	2 GB
Database Server	2GB	6 GB

4.1 DATABASE SERVER CAPCITY ESTIMATION

The database server table size capacity estimation is based on the information provided by CBER and CDER. The actual database size will be monitored on a monthly basis and actual table size capacity will be provided to the FDA as the tables begin to be populated.

(1) CDER and CBER will each receive 30 new applications per year (Total: 60 applications per year).

(2) CDER and CBER will each receive 500 submissions per month (Total: 1000 submissions per month).

(3) There are total 600 reviewers in CDER and CBER. Each reviewer will review 200 submissions per year and download 500 files for each submission.

The above estimates have been used to estimate the database size for the following tables:

Table Name	Average Row Size	Calculation	Total Est Size
Attribute _Info	70 bytes/row, index size 4 bytes/row	12 mos * 1000 subms/month * 312 elements /subm * 5 attributes (rows) /element * 74 bytes/row	1.4 GB
Element _Info	40 bytes/row, index size 4 bytes/row	12 mos * 1000 subms/month * 2 (element_tag + leaf) /element * 312 elements (rows) /submn * 44 bytes/row	0.3 GB
Application _Info	70 bytes/row, index size 3 bytes/row	12 mos * 60 applications (rows)/ year * 73 bytes/row	< 1.0 MB
Submission _Info	120 bytes/row, index size 3 bytes/row	12 months * 1000 subms (rows)/application * 123 bytes/row	1.5 MB
Event _Info	80 bytes/row, index size 3 bytes/row	12 months * 1000 submissions/month * 100 errors (rows)/submission * 83 bytes/row	100 MB
Download _Record	70 bytes/row, index size 4 bytes/row	600 reviewer * 200 submissions/reviewer * 500 files (rows)/submission * 74 bytes/row	4 GB
Total			**6.5 GB**

4.2 APPLICATION REQUIREMENTS

Table 4.2-1 provides the memory and disk space requirements for the applications used in the EVS deployment environment.

Table 4.2-1: Application Memory and Disk Space

Software	Resource	Memory	Disk Space
Solaris 9	Solaris[tm] 9 Operating Environment Data Sheet http://wwws.sun.com/software/solaris/ds/ds-sol9oe/index.html	128 MB	1 GB
Oracle 8i	Oracle 8i Installation Guide release 3 (8.1.7) for Sun Sparc http://download-east.oracle.com/docs/pdf/A85471_01.pdf	256MB	1.160 GB
Oracle9i Application Server	Oracle9i Application Server Installation Guide: Release 2 (9.0.2) for Sun SPARC Solaris http://technet.oracle.com/docs/products/ias/doc_library/90200sol_otn/install.902/install/requirements.htm#1035567	256MB	435 MB
Net Link	SolarisTM PC NetLink 2.0 Installation Guide http://docs.sun.com/source/816-0327-10/install_.htm#996879	48 MB	NA

4.3 DATABASE REQUIREMENTS

The production database configuration is dependent on the following requirements:

- Oracle 9.0.1.3 on Sun SPARC Solaris
- Locally Managed Tablespaces with uniform extent sizes: app_data_small01, app_index_small01, med01, large01, xlarge01, etc.
- RAID 1+0 (All the files on one stripe set, and to multiplex redo/archive and control files on another stripe set).

Details related to the database configuration sizing and disk space estimates are filed separately.

5. METRICS

A set of variables will track EVS usage on a monthly basis using Excel. Over time, the variables will help identify trends on EVS usage and prevent reaching capacity. Examples of variables include number of users, number of files downloaded per user per month. The following metrics have been identified to track initial EVS activities:

- Number of users per month
- Number of new users per month
- Number of computers used onsite
- Number of files downloaded per user
- Total number of files downloaded per Center
- Number of elements per XML file
- Total number of elements per submission

These may be modified to accommodate EVS needs as activity increases.